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### NOTICE OF ALLOWANCE AND FEE(S) DUE

30671 7590 01242011 DITTHAVONG MORI & STEINER, P.C. 918 Prince Street Alexandria. VA 22314

EXAMINER				
ARIA	NI, KADE			
ART UNIT	PAPER NUMBER			
1651	•			

DATE MAILED: 01/24/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,184	06/13/2007	Satoru Yamagami	01125_1000	3525

TITLE OF INVENTION: LAMINATE OF CULTURED HUMAN CORNEAL ENDOTHELIAL CELLS LAYER AND METHOD FOR MANUFACTURING SAME

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	04/25/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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appropriate. All further indicated unless correcte maintenance fee notifical	correspondence includir ed below or directed oth	or transmitting the 1880 ig the Patent, advance of nerwise in Block 1, by (a	rders and notification of r a) specifying a new corres	naintenance fees w pondence address;	ill be n and/or	nailed to the current (b) indicating a sepa	correspondence address as trate "FEE ADDRESS" for
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							(Signature)
							(Date)
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nonprovisional	NO	\$1510	\$300	\$0		\$1810	04/25/2011
EXAM	INER	ART UNIT	CLASS-SUBCLASS				
ARIANI	, KADE	1651	424-423000				
"Fee Address" ind. PTO/SB/47; Rev 03-0 Number is required.  3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address 12 or more recent) attach ND RESIDENCE DATA	nge of Correspondence  Indication form ed. Use of a Customer  A TO BE PRINTED ON	For printing on the p     (1) the names of up to or agents OR, alternative     (2) the name of a single registered attorney or a 2 registered patent attolisted, no name will be     THE PATENT (print or type.)	3 registered patent ely, e firm (having as a gent) and the name neys or agents. If r printed.	membe s of up to name	era 2eto	
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	s SMALL ENTITY state	is. See 37 CFR 1.27.	☐ b. Applicant is no lon				
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than t Office.	ne applicant; a regis	tered a	ttorney or agent; or th	ne assignee or other party in
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10/590,184	06/13/2007	Satoru Yamagami	01125_1000	3525		
30671 75	590 01/24/2011		EXAMINER			
DITTHAVONG MORI & STEINER, P.C.			ARIANI, KADE			
918 Prince Street			ART UNIT	PAPER NUMBER		
Alexandria, VA 22314		·	1651			

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 408 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 408 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)	
10/590,184	YAMAGAMI ET AL.	
Examiner	Art Unit	

KADE ARIANI I 1651 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTQL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. X This communication is responsive to the telephonic interview with Attorney Christopher Ward on 1/14/2011. The allowed claim(s) is/are 1-17. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) Some\* c) None of the: Certified copies of the priority documents have been received. 2. 

Certified copies of the priority documents have been received in Application No. \_\_\_\_ 3. 
☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \* Certified copies not received: \_\_\_\_\_. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. T DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413). Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. T Examiner's Statement of Reasons for Allowance of Biological Material 9. 

☐ Other /Kade Ariani/ Primary Examiner, Art Unit 1651

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

# Telephonic Interview Summery

Authorization for this examiner's amendment was given in a telephone interview with Applicant's Attorney Christopher D. Ward on January 14, 2011.

## Amendments to the Claims

Claims 1-17 are allowed.

In claim 1 (line 1) delete "sheet" and insert –sheet that has been coated with an adhesive factor or a bioadhesive – in its place.

In claim 3 (lines 1-2) delete "transparent type I collagen sheet has an adhesive factor or bioadhesive layer" and insert —adhesive factor or bioadhesive layer is— in its place.

In claim 4 (line 1) delete "an" and insert -said-- in its place.

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In claim 6 (line 1) delete "cultured human corneal endothelial cells" and insert --a cultured layer of human corneal endothelial cells on a transparent type I collagen sheet- in its place.

In claim 6 (line 5 continued on the next page) delete "human" and insert --a solution containing human--.

In claim 6 (line 5 continued on the next page) delete "cultured layer of human corneal endothelial cells" and insert --laminate comprising a cultured layer of human corneal endothelial cells and said transparent type I collagen sheet having a thickness ranging from 5 to 50 micrometers-- in its place.

In claim 8 (line 2) delete "a" and insert -said-- in its place.

In claim 10 (line 2) delete "a culture" and insert --the-- in its place, and (line 3) delete "a" and insert --the-- in its place.

In claim 11 (line 3) delete "culture".

In claim 16 (line 3) after "sheet" insert --into the anterior chamber of an eye from which the Descemet's membrane was removed--.

In claim 16 (lines 3-4) delete "transplanting the laminate by inserting it into the anterior chamber" and insert --adding fibronectin to said laminate and inserting the laminate into the anterior chamber-- in its place.

In claim 17 (line 1) delete "comprising fixing the inserted laminate to the posterior corneal stroma" and insert —wherein the inserted laminate is attached and fixed to the posterior corneal stroma—in its place.

#### Examiner Comments

Application/Control Number: 10/590,184

Art Unit: 1651

The rejection of claims 1-17 under 35 U.S.C. 102 (a) as being anticipated by Mimura et al. (in the Office Action mailed on 6/9/2010) is withdrawn in view of the priority date and due to the filing of the translation of the certified copy of foreign priority document together with the statement that the translation is accurate (on 09/09/2010).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KADE ARIANI whose telephone number is (571)272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-2720926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kade Ariani/ Primary Examiner, Art Unit 1651